

## **Nutritional Therapy for Phenylketonuria (PKU)**

Since November 1, 2005, specific enteral nutrition products became restricted and required a separate SAR. At that time, enteral nutrition products for PKU were classified under a general subject designation of Nutritional Therapy, Special Formulations. Therefore, PKU enteral nutrition products, under this broad designation, became restricted.

Recently, it has come to the attention of the Branch that newer and some older PKU products were no longer located under the designation of Nutritional Therapy, Special Formulations. As a consequence, these products were not restricted. Not knowing which PKU products were restricted created some confusion and difficulty with authorizations. The restriction of the additional PKU products now makes the authorization process consistent for metabolic enteral nutrition products.

Effective immediately, the following products have been restricted and will require a separate SAR:

EAA POWDER
LOPHLEX PACKET
PERIFLEX ADVANCE PKU POWDER
PERIFLEX POWDER
PHENEX-1 POWDER
PHENEX-2 POWDER
PHENYL-FREE 2 POWDER
PHENYL-FREE 2HP POWDER
PHENYL-FREE POWDER 1
PHENYLADE PHEBLOC TABLET (formerly known as Prekunil tablet)
PHLEXY-10 500 MG CAPSULE
PHLEXY-10 BAR

PHLEXY-10 DRINK MIX POWDER

PHLEXY-10 TABLET

PKU 2 POWDER

PKU 3 POWDER

PKU COOLER 15 LIQ COOLER

PKU EXPRESS LIQ COOLER

PKU EXPRESS POWDER

PREKUNIL TABLET (new NDC)

XPHE ANALOG POWDER

XPHE MAXAMAID POWDER

XPHE MAXAMUM DRINK

XPHE MAXAMUM PACKET

XPHE MAXAMUM POWDER